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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,336	01/31/2001	Jose Pozuelo	POZ 2 0004-3	4263

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EXAMINER
CELSA, BENNETT M

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary	Application No. 09/773,336	Applicant(s) Pozuelo, J.
	Examiner Bennett Celsa	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above, claim(s) *1-8 and 16-19* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *9-15* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the claims

Claims 1-19 are currently pending.

Claims 9-15 are under consideration to the extent of the elected invention.

Claims 1-8 and 16-19 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restriction

1. Applicant's election of Group III (claims 9-15 in part to treating narcotic addiction by administering AMPT and Haldol) in Paper No. 6 (dated 10/7/02) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 9-13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pozuelo US Pat. No. 4,117,161 (9/78) and Pachter et al. US Pat. No. 3,819,635 (6/74) .

The present claims (e.g. claims 9-13 and 15) are directed to a method of treating narcotic addiction (e.g. addiction to heroin or cocaine or amphetamines or marijuana) by administering:

I. alpha-methyl-para tyrosine (AMPT) and

II. 4-[4-(p-chlorophenyl)-4-hydroxy-piperidino]-4'-fluorobuyrophenone (HALDOL or HALOPERIDOL).

Pozuelo teaches the use of AMPT to treat narcotic (e.g. morphine, marijuana etc.) and/or amphetamine addiction by treating the craving and withdrawal symptoms when a patient is deprived of such narcotics and/or amphetamines. Pozuelo further teaches AMPT amounts (e.g. see patent claims) within the presently claimed scope, while further teaching that the "[T]he exact amount to be utilized varies from person to person depending on the degree of addiction and is determined emperically". See e.g. col. 2, especially lines 19-30.

The Pozuelo reference differs from the presently claimed invention by failing to further utilize HALOPERIDOL.

However, Pachter et al. teach that "[I]t has been reported in the literature that ... HALOPERIDOL ... has found some experimental use in the alleviation of narcotic addiction withdrawal symptoms" and it is therefore preferred to combine HALOPERIDOL with narcotic antagonists (such as the Pachter et al. Reference 14-Hydroxymorphinan derivatives which are analogous in structure to NALTREXONE: e.g. see formulas in col. 4; and Table 5 reference to

"NALOXONE") in order to produce a product preventing narcotic abuse and providing supportive therapy in the absence of opiates. See Pachter et al. Col. 16, especially lines 2-15. The Pachter reference teaches HALOPERIDOL oral administration of 0.5-5 mg two or three times daily (e.g. see col. 16, lines 15-20).

To the extent that the Pacther reference dosage differs from the HALOPERIDOL dosage presently claimed, in combination with AMPT , it is noted that the exact amount of HALOPERIDOL to be utilized in a combined formulation would vary from person to person depending on the degree of addiction and is determined emperically (e.g. see Pozuelo at col. 2, especially lines 19-30) and thus optimum dosage would be obvious to determine by a medical practitioner.

Accordingly, one of ordinary skill in the art at the time of applicant's invention would have been motivated to administer Pozuelo's AMPT composition with Pachter's HALOPERIDOL composition, since both treat narcotic addiction (e.g. address narcotic withdrawal symptoms); and in order to obtain the combined additive effect of each of the drugs taken separately.

Courts have determined that it is indeed obvious to one of ordinary skill in the art to co-administer two (or more) pharmaceuticals, each of which is taught to have the same utility, when they are individually known to have that utility, absent unexpected results. See e.g. *In re Kerhoven*, 626 F.2d 846,205 USPQ 1069 (CCPA 1980).

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to formulate dually administer AMPT and HALOPERIDOL for treating narcotic addiction as presently claimed.

4. Claims 9-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pozuelo US Pat. No. 4,117,161 (9/78) and Pachter et al. US Pat. No. 3,819,635 (6/74) as applied to claims 9-13 and 15 above, and further in view of Gooberman et al. US Pat. No. 5,789,411 (8/98: filed 6/96 or earlier) and/or Archer US Pat. No. 5,760,044 (6/98: filed 5/96) .

The present claims (e.g. claims 9-13 and 15) are directed to a method of treating narcotic addiction (e.g. addiction to heroin or cocaine or amphetamines or marijuana) by administering:

I. alpha-methyl-para tyrosine (AMPT) and

II. 4-[4-(p-chlorophenyl)-4-hydroxy-piperidino]-4'-fluorobuyrophenone (HALDOL or HALOPERIDOL);

and optionally further including NALTREXONE (e.g claim 14).

The combined Pozuelo and Pachter patent reference teaching (discussed above and hereby incorporated by reference in its entirety) differs from the presently claimed invention (e.g claim 14) in failing to additionally administer NALTREXONE to treat narcotic addiction.

However, the Archer Patent teaches the administration of NALTREXONE or NALOXONE , separately, or in combination with a morphine derivative (e.g. see formula in

abstract) to treat cocaine and amphetamine dependency. See e.g. Archer at col. 12; patent claims 18 and 20.

Similarly, Gooberman et al. patent teach administering NALTREXONE for treating opioid (e.g heroin) withdrawal. See e.g. col. 5 and Examples (e.g. example 1); patent claims 7, 9, 15, 23,29).

Accordingly, one of ordinary skill in the art at the time of applicant's invention would have been motivated to administer NALTREXONE along with AMPT and HALOPERIDOL in order to further treat narcotic addiction (e.g. to address narcotic withdrawal symptoms) in order to obtain the combined additive effect of each of the drugs taken separately.

Courts have determined that it is indeed obvious to one of ordinary skill in the art to co-administer two (or more) pharmaceuticals, each of which is taught to have the same utility, when they are individually known to have that utility, absent unexpected results. See e.g. *In re Kerhoven*, 626 F.2d 846,205 USPQ 1069 (CCPA 1980).

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to additionally administer NALTREXONE along with AMPT and HALOPERIDOL for treating narcotic addiction as presently claimed.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

December 12, 2002

BENNETT CELSA
PRIMARY EXAMINER